# IAP6 Rec'd PCT/PTO 04 JUN 2007

	TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371				. CUSTOMER NO. <b>22,852</b> ATTORNEY'S DOCKET NUMBER <b>09707.0011-00000</b>			
					U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/579,294			
				November 12, 2004	PRIORITY DATE CLAIMED November 14, 2003			
CI	ELL		RE METHOD, THR	EE-DIMENSIONAL CELL CULT ND TISSUE TRANSPLANTATION	URE METHOD, THREE-DIMENSIONAL			
-		NT(S) FOR I	DO/EO/US	TANISHITA; 3) Mariko IKED				
Apr	Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:							
1.		This is a F	IRST submission of items c	oncerning a filing under 35 U.S.C 371.				
2.	$\boxtimes$	This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.						
3.		This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items						
4.		(5), (6), (9) and (21) indicated below. The US has been elected (Article 31).						
5.				as filed (35 U.S.C. 371 (c)(2)).				
	<u></u>	a.		d only if not communicated by the International B	Bureau).			
		b. 🗍	has been communicated b					
		c. $\square$		ication was filed with the United States Receiving	g Office (RO/US).			
6.				International Application as filed (35 U.S.C. 371)				
		a.	is attached hereto.					
		ь. П	has been previously subm	itted under 35 U.S.C. 154(d)(4).				
7.		Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).						
	_	a. are attached hereto (required only if not communicated by the International Bureau).						
		b.  have been communicated by the International Bureau.						
		c.  have not been made; however, the time limit for making such amendments has NOT expired.						
		d.  have not been made and will not be made.						
8.		An English	n language translation of the	amendments to the claims under PCT Article 19	(35 U.S.C. 371 (c)(3)).			
9.		An oath or	declaration of the inventor(	s) (35 U.S.C. 371 (c)(4)).				
10.		An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).						
Iter	ns 11 1	to 20 below	concern document(s) or i	nformation included:				
11.		Information	n Disclosure Statement und	er 37 CFR 1.97 and 1.98				
12.		An assignr	ment document for recording	g. A separate cover sheet in compliance with 37	CFR 3.28 and 3.31 is included.			
13.		A prelimina	A preliminary amendment.					
14.		An Applica	An Application Data Sheet under 37 CFR 1.76.					
15.		A Substitute specification.						
16.		A power of attorney and/or change of address letter.						
17.	$\boxtimes$	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.						
18.		A second copy of the published International Application under 35 U.S.C. 154 (d)(4).						
19.		A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4).						
20.		Other items or information: Petition for Extension of Time (One Month)						
		a. 🔲	Copy of cover page of Inte	ernational Publication No. WO 2005/047496	<b>A1.</b>			
1		b. ⊠	Sequence Listing in hardo					
		c. ⊠ d. ⊠	Copy of Notification of Mis Sequence Listing Statement	· ·				

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)			INTERNATIONAL APPLICATION NO.			ATTORNEY'S DOCKET NUMBER		
10/579,294			PCT/JP2004/017227			09707.0011-00000		
		have been submitted:				CALCULATIONS	PTO Use Only	
21. 🔲	BASIC NATIONAL F	FEE (37 CFR 1.492(a)):		\$300.00		\$		
22 🗆	Examination fee (370	OFR 1.492(c))						
ָל	by IPEA/US indicates all c	by ISA/US or the International policies of PC	CT Article 33(1)-(4)	\$0		•		
All other	situations			\$200		\$ 3	<u> </u>	
23. Search fee (37 CFR 1.492(b))  If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)								
All other	situations			\$500		\$	<del> </del>	
- Add	1 High	**************************************	1, 22 and 23 =			\$		
∐ Add	listing in compliance electronic medium) (	ion and drawings filed in paper with 37 CFR 1.821(c) or (e) o (37 CFR 1.492(j)). each additional 50 sheets of p	or computer program listing in					
	Total Sheets	Extra Sheets	Number of each additional thereof (round up to a who		Rate			
					x \$250.00	\$		
Extensio	on of Time Fee (One Mon	ath)				\$ 120.00		
	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			<u> </u>	
Total Cla	aims			x \$50.0		\$		
Independ	ident Claims			x \$200.0		\$		
MULTIPI	PLE DEPENDENT CLAIM	I(S) (if applicable)		+\$360.0	10	\$		
			TOTA	L OF ABOVE CALC	ULATIONS =	\$ 120.00		
Appli Appli	icant claims small entity s	status. See 37 CFR 1.27. Fe	es above are reduced by 1/2.			\$ - 60.00		
				S	SUBTOTAL =	\$ 60.00		
Processi 1.492(i)).	_	rnishing the English translation	n later than 30 months from th	e earliest priority date	e (37 CFR +	\$		
				TOTAL NATIO	ONAL FEE =	\$		
	recording the enclosed as neet (37 CFR 3.28, 3.31).	ssignment (37 CFR 1.21 (h)). . \$40.00 per property.	The assignment must be acc	companied by an app	ropriate +	\$		
				T	OTAL FEE =	\$ 60.00		
						Amount to be refunded:	S	
						charged:	\$	
a. 🔲	A check in the amount of	of \$ to cover the ab-	pove fees is enclosed.					
b. 🔯	Please charge my Depo A duplicate copy of this	osit Account No. <u>06-0916</u> in the sheet is enclosed.	ne amount of \$60.00 to cover	the above fee.				
c. 🛭	c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0916. A duplicate copy of this sheet is enclosed.							
d. 🔲	d.  Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.							
NOTE:	NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.							
SEND A	ALL CORRESPONDENC	CE TO:	Tint	! B/LC	7/			
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.  901 New York Avenue, N.W.  Washington, DC 20001-4413  Timotoy B. Donaldson, Reg. No.					. 43,592	!		
DATED <sup>.</sup>	June 4, 2007		NAME/HE	GISTRATION NUMB	ER			

,	TRAN	SMITTAL LETTER TO THE UNITED S (DO/EO CONCERNING A SUBMISSI	CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER 09707.0011-00000				
				U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/579,294			
INTERNATIONAL APPLICATION NO. PRIORITY DATE CLAIMED  PCT/JP2004/017227 November 12, 2004 PRIORITY DATE CLAIMED  November 14, 2003							
CE	LL C	INVENTION CULTURE METHOD, THR E, ARTIFICIAL ORGAN AN	EE-DIMENSIONAL CELL CULT ND TISSUE TRANSPLANTATIO	TURE METHOD, THREE-DIMENSIONAL N METHOD			
	APPLICANT(S) FOR DO/EO/US  1) Ryo SUDO; 2) Kazuo TANISHITA; 3) Mariko IKEDA; 4) Toshihiro MITAKA						
Appl	icant(s		Designated/Elected Office (DO/EO/US) the following				
1.		This is a FIRST submission of items of	oncerning a filing under 35 U.S.C 371.				
2.	$\boxtimes$		submission of items concerning a submission (	under 35 U.S.C. 371.			
3.		This is an express request to begin na	itional examination procedures (35 U.S.C. 371)				
4.		(5), (6), (9) and (21) indicated below. The US has been elected (Article 31).					
<b>5</b> .		A copy of the International Application					
J.	لسا	• •	ed only if not communicated by the International	Bureau).			
		_	by the International Bureau.				
		_	lication was filed with the United States Receiving	ing Office (RO/US).			
6.		<del></del>	e International Application as filed (35 U.S.C. 37				
		a. is attached hereto.					
			nitted under 35 U.S.C. 154(d)(4).				
7.		_	rnational Application under PCT Article 19 (35 t	J.S.C. 371 (c)(3)).			
			red only if not communicated by the Internation				
		<u>_</u>	by the International Bureau.				
			ever, the time limit for making such amendmen	ts has NOT expired.			
		d. have not been made and v					
8.		_		19 (35 U.S.C. 371 (c)(3)).			
9.		An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).  An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).					
10.		An earth of declaration of the inventor(s) (35 0.5.0. 371 (c)(4)).  An English language translation of the annexes of the International Preliminary Examination Report under PCT  Article 36 (35 U.S.C. 371 (c)(5)).					
Item	ıs 11 t	to 20 below concern document(s) or	information included:				
11.		Information Disclosure Statement und	ler 37 CFR 1.97 and 1.98				
12.		An assignment document for recordin	g. A separate cover sheet in compliance with 3	37 CFR 3.28 and 3.31 is included.			
13.		A preliminary amendment.					
14.		An Application Data Sheet under 37 CFR 1.76.					
15.		A Substitute specification.					
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19		A second copy of the English languag	e translation of the international application 35	U.S.C. 154 (d)(4).			
20.	፟	Other items or information: Petition	for Extension of Time (One Month)				
		a.   Copy of cover page of Interest	ernational Publication No. WO 2005/047490	6 A1.			
		b. Sequence Listing in hardo					
		c.	ssing Requirements.				
ļ		d. 🛛 Sequence Listing Stateme	ent.				



### JNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/579,294

Ryo Sudo

09707.0011

PCT/JP04/17227

INTERNATIONAL APPLICATION NO.

22852 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER

LLP

901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 RECEIVED

MAR 0 5 2007

11/12/2004 11/14/2003

PRIORITY DATE

**CONFIRMATION NO. 6583** 



\*OC000000022719016\*

I.A. FILING DATE

Date Mailed: 03/02/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT AND DUNNER, LLP

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 05/15/2006
- English Translation of the IA filed on 05/15/2006
- Copy of the International Search Report filed on 05/15/2006
- Preliminary Amendments filed on 05/15/2006
- Information Disclosure Statements filed on 05/15/2006
- Biochemical Sequence Diskette filed on 05/15/2006
- U.S. Basic National Fees filed on 05/15/2006
- Priority Documents filed on 05/15/2006
- Specification filed on 05/15/2006
- Claims filed on 05/15/2006
- Abstracts filed on 05/15/2006
- Drawings filed on 05/15/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

#### **SUMMARY OF FEES DUE:**

Total additional fees required for this application is \$65 for a Small Entity:

- \$65 Surcharge.
  - A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <a href="http://www.uspto.gov/ebc.">http://www.uspto.gov/ebc.</a>

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

TAMALA D HOLLAND

Telephone: (703) 308-9140 EXT 209

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/579,294	PCT/JP04/17227	09707.0011

# STIC Biotechnology Systems Branch

# RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10549
Source:

Date Processed by STIC:

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,

2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.4.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/10/06



IFWP

RAW SEQUENCE LISTING

DATE: 05/23/2006

PATENT APPLICATION: US/10/579,294 TIME: 14:29:58

Input Set : A:\PTO.KD.txt

Output Set: N:\CRF4\05232006\J579294.raw

3 <110> APPLICANT: KEIO UNIVERSITY 5 <120> TITLE OF INVENTION: Methods of cell culture, cell 3D culture, and tissue transplantation, and 3D tissue and artificial organ made thereby 9 <130> FILE REFERENCE: PCT835

C--> 11 <140> CURRENT APPLICATION NUMBER: US/10/579,294

C--> 11 <141> CURRENT FILING DATE: 2006-05-15

11 <150> PRIOR APPLICATION NUMBER: JP 2003/385677 12 <151> PRIOR FILING DATE: 2003-11-14

14 <160> NUMBER OF SEQ ID NOS: 12

16 <170> SOFTWARE: PatentIn version 3.1

Does Not Comply Corrected Diskette Needed

#### **ERRORED SEQUENCES**

156 <210> SEQ ID NO: 12
157 <211> LENGTH: 20
158 <212> TYPE: DNA
159 <213> ORGANISM: Artificial Sequence Source
161 <220> FEATURE.

P\S explain

P\S explain

P\S explain

P\S explain

F genetic

MAterial. 161 <220> FEATURE: 162 <223 > OTHER INFORMATION: (P12) 164 <400> SEQUENCE: 12 165 tccaccaccc tgttqctgta B--> 170 (continued from previous page) B--> 171 (continued on next page) B--> 174 (continued from previous page) B--> 175 (continued on next page) pis delete

157-9,296 15 explain source of genetic material <210> <211> <212> <2135 Artificial Sequence PIS delete <223> Inventor: Sudo, Ryo Inventor: Tanishita, Kazuo Inventor: Ikeda, Mariko Inventor: Mitaka, Toshihiro <220> Invalid Response <400> 1 aaggcacccc gattactccg eabore erron is seen Globally Anroughort The sequence, Seeitem#11 on error Summary sheat

RAW SEQUENCE LISTING ERROR SUMMARY PATENT APPLICATION: US/10/579,294

DATE: 05/23/2006 TIME: 14:29:59

Input Set : A:\PTO.KD.txt

Output Set: N:\CRF4\05232006\J579294.raw

Invalid Line Length:

The rules require that a line not exceed 72 characters in length. This includes spaces.

Seq#:1; Line(s) 5

VERIFICATION SUMMARY
PATENT APPLICATION: US/10/579,294

DATE: 05/23/2006 TIME: 14:29:59

Input Set : A:\PTO.KD.txt

Output Set: N:\CRF4\05232006\J579294.raw

L:11 M:270 C: Current Application Number differs, Replaced Current Application No

L:11 M:271 C: Current Filing Date differs, Replaced Current Filing Date

L:170 M:334 B: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4

L:171 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12

L:171 M:334 E: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4

L:174 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12

L:174 M:334 B: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4

L:175 M:336 W: Invalid Amino Acid Number in Coding Region, SEQ ID:12

L:175 M:334 B: (2) Invalid Amino Acid in Coding Region, NUMBER OF INVALID KEYS:4